Docket No.: CI-0019C4 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	:	
Randall S. KENT and Edward HORTON	:	
Serial No.:	Continuation App of 09/533,547 :	
Filed:	October 29, 2003	: Customer No.: 34610

For: METHODS FOR STERILIZING BIOLOGICAL MATERIALS

INFORMATION DISCLOSURE STATEMENT

U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, Virginia 22202

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).

_ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).

_ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

_ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

_ c. Attached is our check no. _____ in the amount of $180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.

_ 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ___ in the amount of $180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).

_ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

_ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).

X 4. Copies of the references were cited by or submitted to the Office in parent application No. 09/533,547, filed March 23, 2000, which is relied upon for an earlier filing date under 35 U.S.C. §120. Thus, copies of these references are not attached. 37 C.F.R. §1.98(d).

X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP

Donald R. McPhail
Registration No. 35,811
Timothy M. Speer

P.O. Box 221200
Chantilly, Virginia 20153-1200
703 502-9440
Date: October 29, 2003

DRM\TMS:dcp

Please direct all correspondence to Customer Number 34610

LIST OF PRIOR ART CITED BY APPLICANT
SUBSTITUTION FOR
(PTO-1449)

ATTY. DOCKET NO.	APPLN. SERIAL NO.
CI-0019C4	**Cont. of 09/533,547**
APPLICANT: **Randall S. KENT and Edward HORTON**	
FILING DATE: **October 29, 2003**	GROUP: **1744**

U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A1	RE 23,195	02/1950	Arno Brasch			
	A2	2,832,689	04/1958	Bernard E. Proctor et al.			
	A3	2,920,969	01/1960	E.S. Stoddard			
	A4	2,962,380	11/1960	J.H. Wertheim			
	A5	3,620,944	11/1971	Keiko Tanito			
	A6	3,743,480	07/1973	John D. Falk			
	A7	3,779,706	12/1973	Nablo			
	A8	4,136,094	01/1979	Condie			
	A9	4,251,437	02/1981	Rasmussen et al.			
	A10	4,282,863	08/1981	Beigler et al.			
	A11	4,330,626	05/1982	Blair et al.			
	A12	4,336,247	06/1982	Eriksen			
	A13	4,370,264	01/1983	Kotitschke et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B1	US2002/ 0064807 A1	05/30/02	BADYLAK et al.	435	34	11/14/01

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C1						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D1	2,056,619	10/1991	Canada				
	D2	310 316	04/1989	Europe				
	D3	334 679	09/1989	Europe				
	D4	919 198 A2	06/1999	Europe (Abstract)			X	
	D5	919 198 A3	06/1999	Europe (Abstract)			X	

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E1	AABB FDA Liaison Meeting, ABC Newsletter, p. 14 (December 12, 1997)
	E2	Alladine, M.F. et al., γ-Radiation Damage to Starr-Edwards Valves, The Lancet, 1:594 (1968)
	E3	Alper, T. et al., Protection by Anoxia of the Scrapie Agent and some DNA and RNA Viruses Irradiated as Dry Preparations, J. Gen. Virol., 3:157-166 (1968)

EXAMINER	DATE CONSIDERED

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U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A14	4,409,105	10/1983	Hayashi et al.			
	A15	4,472,840	09/1984	Jefferies			
	A16	4,620,908	11/1986	Van Duzer			
	A17	4,784,850	11/1988	Abraham			
	A18	4,798,611	01/1989	Freeman Jr.			
	A19	4,865,602	09/1989	Smestad et al.			
	A20	4,931,361	06/1990	Baldeschwieler etal.			
	A21	4,933,145	06/1990	Uchida et al.			
	A22	4,946,648	08/1990	Dichtelmüller et al.			
	A23	4,963,356	10/1990	Calenoff et al.			
	A24	5,000,951	03/1991	Bass et al.			
	A25	5,012,503	04/1991	Nambu et al.			
	A26	5,044,091	09/1991	Ueda et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B2	US2001/ 0049141 A1	12/06/01	FIKE et al.	435	384	02/13/98

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C2						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D6	11-216147	08/1999	Japan (Abstract)			X	
	D7	1321420-A	07/1987	Soviet Union (Abstract)			X	
	D8	WO 90/00907	02/1990	PCT Int'l				
	D9	WO 91/16060	10/1991	PCT Int'l				
	D10	WO 95/03071	02/1995	PCT Int'l				

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*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E4	Alper, T. et al., Does the Agent of Scrapie Replicate Without Nucleic Acid?, Nature, 214:764-766 (1967)
	E5	Alper, T. et al., The Exceptionally Small Size of the Scrapie Agent, Biochemical and Biophysical Research Communications, 22:278-284 (1966)
	E6	Alper, T. et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, J. Gen. Virol., 41:503-516 (1978)

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*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A27	5,106,619	04/1992	Wiesehahn et al.			
	A28	5,134,295	07/1992	Wälischmiller			
	A29	5,185,371	02/1993	Rubinstein			
	A30	5,226,065	07/1993	Held et al.			
	A31	5,283,034	02/1994	Okrongly et al.			
	A32	5,362,442	11/1994	Kent			
	A33	5,418,130	05/1995	Platz. et al.			
	A34	5,460,962	10/1995	Kemp			
	A35	5,510,122	04/1996	Sreebny et al.			
	A36	5,548,066	08/1996	Leneau et al.			
	A37	5,603,894	02/1997	Aikus et al.			
	A38	5,609,864	03/1997	Shanbrom			
	A39	5,637,451	06/1997	Ben-Hur et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B3	US2002/ 0106394 A1	08/08/02	TUCKER et al.	424	423	09/18/01

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C3						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D11	WO 00/25839	03/2000	PCT Int'l (Abstract)			X	
	D12	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X	
	D13	WO 01/12318A1	02/2001	PCT Int'l				
	D14	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X	
	D15	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X	

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*EXAMINER'S INITIALS	CITE NO.	**(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)**
	E7	Akkus, O. et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, J. Orthapaedic Research, 19:927-934 (2001) (Elsevier Science Ltd.)
	E8	Aparicio, S.R. et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, J. Path., 115:147-162 (1975)
	E9	Baksa, J. et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, Magyar Traumatologia, 19:138-145 (1976)

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	A40	5,643,464	07/1997	Rhee et al.			
	A41	5,712,086	01/1998	Horowitz et al.			
	A42	5,730,933	03/1998	Peterson			
	A43	5,817,528	10/1998	Böhm et al.			
	A44	5,837,313	11/1998	Ding et al.			
	A45	5,856,172	01/1999	Greenwood et al.			
	A46	5,881,534	03/1999	Ahlqvist et al.			
	A47	5,981,163	11/1999	Horowitz et al.			
	A48	5,986,168	11/1999	Noishiki			
	A49	5,989,498	11/1999	Odland			
	A50	6,010,719	01/2000	Remon et al.			
	A51	6,046,024	04/2000	Burton et al.			
	A52	6,049,025	04/2000	Stone et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B4	US 2002/ 0188319 A1	12/12/02	MORRIS et al.	606	213	06/10/02

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C4						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D16	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X	
	D17	WO 01/49219A1	07/2001	PCT Int'l				
	D18	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X	
	D19	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X	
	D20	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X	

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*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E10	Baldwin, M.L. et al., Irradiation of Blood Components, pp. 10-78 (1992) (American Association of Blood Banks)
	E11	Baquey, C. et al.., Radiosterilization of Albuminated Polyester Prostheses, Biomaterials, 8:185-189 (1987)
	E12	Bassin, R.H. et al., Abrogation of Fv-1^b Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, Journal of Virology, 26:306-315 (1978) (American Society for Microbiology)

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U.S. PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	A53	6,060,233	05/2000	Wiggins			
	A54	6,066,626	05/2000	Yew et al.			
	A55	6,087,141	07/2000	Margolis-Nunno et al.			
	A56	6,120,592	09/2000	Brault et al.			
	A57	6,159,490	12/2000	Deghenghi			
	A58	6,171,549	01/2001	Kent			
	A59	6,187,572	02/2001	Platz et al.			
	A60	6,190,855	02/2001	Herman et al.			
	A61	6,197,207	03/2001	Chapman et al.			
	A62	6,203,544	03/2001	Gotzen			
	A63	6,214,534	04/2001	Horowitz et al.			
	A64	6,235,508	05/2001	Sowemimo-Coker et al.			
	A65	6,258,821	07/2001	Stogniew et al.			

U.S. PATENT APPLICATION PUBLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*PATENT APPLN. PUB. NO.	*PUBLICATION DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE
	B5	US2003/ 0068815 A1	04/10/03	STONE et al.	435	325	05/17/02

U.S. PATENT APPLICATIONS

*EXAMINER'S INITIALS	CITE NO.	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	
	C5						

FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
							Yes	No
	D21	EP 0 808 167 B1	06/05/02	EPO				
	D22	EP 0 820 301 B1	07/24/02	EPO				
	D23	WO 00/28552	05/18/00	PCT				
	D24	WO 00/52031	09/08/00	PCT				
	D25	JP 408098688A	04/16/96	Japan			Abs	

OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E13	Beauregard, G. et al., Temperature Dependence of the Radiation Inactivation of Proteins, Analytical Biochemistry, 150:117-120 (1985) (Academic Press Inc.)
	E14	Bedrossian Jr., E.H. et al., HIV and Banked Fascia Lata, Ophthalmic Plastic and Reconstructive Surgery, 7:284-288 (1991) (Raven Press Ltd.)
	E15	Belov, A.A. et al., The Influence of γ-Radiation on Enzyme Activity of Collalitin in the Process of Storage, Radiobiologiia, 30:519-521(1990)

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*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E16	Bingci, L., Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen, Chinese Medical Sciences Journal, 9:100-103 (1994)
	E17	Blakeslee, S., Lack of Oversight in Tissue Donation Raising Concerns, The New York Times, Late Edition, pp. 1, 22 (January 20, 2002) (http://query.nytimes.com)
	E18	Blanchy, B.B. et al., Immobilization of Factor VIII on Collagen Membranes, J. Biomedical Materials Research, 20:469-479 (1986) (John Wiley & Sons, Inc.)
	E19	Block, S.S., Disinfection, Sterilization, and Preservation,, Fourth Edition, pp. 31-33 (1991) (Lea & Febiger) (Philadelphia)
	E20	Bogers, A.J.J.C. et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, Thorac. Cardiovasc. Surgeon, 42:337-339 (1994) (Georg Thieme Verlag Stuttgart)
	E21	Borisova, E.A. et al., Protein Degradation During Interphase Death of Thymocytes Induced by Radation and Dexamethasone, Radiobiologiia, 30:517-519 (1990)
	E22	Boyer, T.D. et al., Radiation Inactivation of Microsomal Glutathione *S*-Transferase, The Journal of Biological Chemistry, 261:16963-16968 (1986)
	E23	Brown, D.R. et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, J. Neurochem., 76:69-76 (2001) (Int'l Society for Neurochem.)
	E24	Brown, P. et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, Transfusion, 38:810-816 (1998)
	E25	Brown, P. et al., Effect of Chemicals, Heat and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, J. Infectious Diseases, 145:683-687 (1982) (University of Chicago)
	E26	Brown, P. et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, Transfusion, 39:1169-1178 (1999)
	E27	Brown, P., The Risk of Blood-Borne Creutzfeldt-Jakob Disease, Advances in Transfusion Safety Dev. Biol., 102:53-59 (1999)
	E28	Burwell, R.G., The Fate of Freeze-Dried Bone Allografts, Transplantation Proceedings, 8(Suppl):95-111 (1976)
	E29	Callegaro, L. et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, The International Journal of Artificial Organs, 6:91-96 (1983) (Wichtig Editore)
	E30	Campalani, G. et al., Aortic Valve Replacement With Frozen Irradiated Homografts, Eur. J. Cardio-thorac. Surg., 3:558-561 (1989) (Springer-Verlag)
	E31	Campbell, D.G. et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, Aust. N.Z. J. Surg., 69:517-521 (1999)
	E32	Chanderkar, L.P. et al.., The Involvement of Aromatic Amino Acids in Biological Activity of Bovine Fibrinogen as Assessed by Gamma-Irradiation, Radiation Research, 65:283-291 (1976) (Academic Press, Inc.)

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OTHER ART

*EXAMINER'S INITIALS	CITE NO.	(AUTHOR, TITLE, DATE, PERTINENT PAGES, PUBLISHER, PLACE OF PUBLICATION)
	E33	Chanderkar, L.P. et al.., Radiation-Induced Changes In Purified Prothrombin and Thrombin, Biochimica et Biophysica Acta, 706:1-8 (1982) (Elsevier Biomedical Press)
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ATTY. DOCKET NO.	APPLN. SERIAL NO.
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FOREIGN PATENT DOCUMENTS

*EXAMINER'S INITIALS	CITE NO.	*PATENT NO.	*PUBLICATION DATE	*COUNTRY	CLASS	SUBCLASS	Translation	
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	D2							
	D3							

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	E2	
	E3	

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